

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical  
Science; Notice of Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical Science.

*General Function of the Committee:* To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on May 21 and 22, 2003, from 8:30 a.m. to 5 p.m.

*Location:* Marriott Washingtonian Center, Ballrooms A, B, C, and D, 9751 Washingtonian Blvd., Gaithersburg, MD.

*Contact Person:* Kathleen Reedy, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, e-mail: REEDYK@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

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Display Date 4-11-03

Publication Date 4-14-03

Certifier N. Hawkins

*Agenda:* On May 21, 2003, the subcommittee will discuss: (1) The mission of the subcommittee; and (2) direction of the Pharmaceutical Current Good Manufacturing Practices (CGMPs) for the 21st Century: A Risk-Based Approach. On May 22, 2003, the subcommittee will discuss: (1) The regulatory approaches regarding aseptic manufacturing; and (2) process analytical technologies and transition from the Advisory Committee for Pharmaceutical Science—Process Analytical Technologies Subcommittee to Manufacturing Subcommittee.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by May 13, 2003. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 13, 2003, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

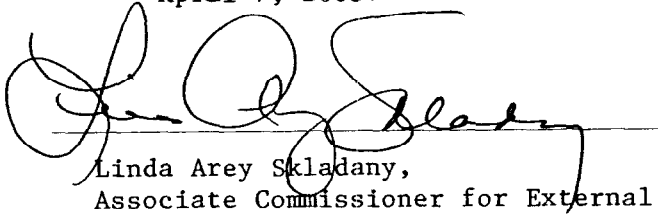
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kathleen Reedy at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act  
(5 U.S.C. app. 2).

Dated:

*April 7, 2003*  
April 7, 2003.



Linda Arey Skladany,  
Associate Commissioner for External Relations.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

**BILLING CODE 4160-01-S**

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*Dawn P. Hawkins*